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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,972

Applicant(s)

ABEL ET AL.

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-92 is/are pending in the application.
- 4a) Of the above claim(s) 48-80 and 92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47 and 81-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/15</u> . | 6) <input type="checkbox"/> Other: _____ |

RD

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-47 and 81-91, in the reply filed on 29 April 2005 is acknowledged. The traversal is on the ground(s) that Feldstein fails to disclose a multitude of recesses forming a two dimensional array of sample compartments for different biological or biochemical recognition elements. This is not found persuasive because Feldstein does teach a multitude of recesses (when the flow cell, 108, is placed on the substrate, 110, recesses are created, Fig. 8a, b; col. 10, lines 22-39) forming a two-dimensional array of sample compartments (sensing surfaces transformed into 2-dimensional array, col. 10, lines 22-39) for different biological or biochemical recognition elements (stripes create the sensing surface, which is transformed into recessed sample compartments with the addition of the flow cell, 110; col. 10, lines 38-39; col. 9, lines 49-55). Claims 48-80 have been withdrawn as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claims 19 and 22 are objected to because of the following informalities: the terms "ôhistidin-tag componentsö" and "ôchemically neutralö" require deletion of "ô" and "ö". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1-47 and 81-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-47 and 81-91 refer to a first optically transparent layer as (a) and a second optically transparent layer as (b) according to Figure 1. Such references are indefinite because it unclear whether these layers are intended to have exactly the same structure as shown in Figure 1. Furthermore, as exemplified in claim 7, Figure 1 comprises a (b') layer between layers a and b, which is not recited in claim 7. It is unclear whether the reference letters are intended to encompass the device of Figure 1, or the features as recited in claims 1-47 and 81-91. Claims 1 and 7 recite "(g) (according to Figure 1)", "(d) (according to Figure 1)", "(a)(according to Figure 1)" and "(b)(according to Figure 1)" which are vague and indefinite because it is unclear what Figure 1 is referring to, and because claims cannot contain Figure numbers. Therefore, the reference characters in claims 1-47 and 81-91 are vague and indefinite because it is unclear what Applicant is claiming as a device.

The phrase "operable to be cleared from received sample or reagent solutions" in lines 12 and 13 of claim 1 is vague because it is unclear whether the sample or reagent solutions are removed from the sample compartments. Claim 1 recites "a sensor platform" in line 11 of the claim, which is indefinite because it is unclear whether the "a sensor platform" of line 11 is the same "a sensor platform" recited in lines 1 and 2. The term "optionally" in line 12 of claim 1 is vague because it is unclear whether washing steps, sample or reagent solutions are being claimed as part of the recited device. The phrase "these sample compartments" in line 10 of the claim is indefinite because it is unclear whether the sample compartments are the same "multitude of sample compartments" recited in line 5 of the claim. Claim 1 recites the limitation "the specific

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recognition" in line 8 and "the excitation" in lines 11 and 12 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 2 is vague because it is unclear whether the recited a single sample compartment is the same sample compartments as the multitude of sample compartments or the sample compartments recited in line 1 of claim 2.

Claim 3 recites the term "several" in line 2, which is vague because it is unclear how many sample compartments comprise measurement areas for referencing. Claim 3 recites the limitation "the same chemical" in line 2 and "the lateral" in line 3 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 4 recites the limitation "the evanescent field" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 8, the term "preferably" is vague because it is unclear whether the transparent thermoplastic plastics must be selected from the recited group.

Claim 13 recites the limitation "the intermediate layer" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 17, the phrase "selective deposition" is vague because it is unclear what is encompassed by selective, and how the elements must be deposited in order to be selective.

With respect to claim 18, the phrase "one or more methods of the group of methods" is vague because it is unclear for what process the group of recited methods is used. It is further unclear how the device of claim 17 can comprise one of the recited methods.

The term "etc." recited in line 5 of claim 19 is vague because it is unclear what is encompassed by biological recognition elements. It is unclear whether biological recognition

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elements are intended to be limited to the elements recited. Claim 19 also recites "(DNA, RNA)", which is vague because it is unclear whether nucleic acids must be selected from DNA and RNA and whether DNA and RNA are claimed as part of the device.

Claims 23-25 recite the limitation "the incoupling" or "the outcoupling" in line 1 of the claims. Claim 25 further recites the limitation "the same" in line 4 of the claim. There is insufficient antecedent basis for these limitations in the claim. There is insufficient antecedent basis for these limitations in the claims.

Claim 30 recites the phrase "for example", which is vague because it is unclear whether the claim is intended to include silica or magnesium fluoride as a lower refractive index. The claim recites the limitation "the excitation wavelength" and "the luminescence" in line 6 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 34 recites the limitation "the range" in line 2 of the claim. Claims 45 and 89 recite the limitation "the locally addressed" in line 2 of the claim. Claims 47 and 91 recite the limitation "the adjustment" in line 2 of the claim. Claim 87 recites the limitation "the supply" in line 3 of the claim. There is insufficient antecedent basis for these limitations in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-34, 38-40, 42-47, 81-84 and 86-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Neuschäfer et al. (WO 96/35940).

Neuschäfer et al. teach a device comprising: a planar optical waveguide as part of a sensor platform, and connected to the platform by means of a sealing medium (pg. 13, last paragraph-pg. 14, line 4), a layer forming a tight seal (10, Fig. 6), the device comprising a multitude of recesses open towards the sensor platform, which form a corresponding multitude of sample compartments in a 2-dimensional arrangement (pg. 14, lines 6-12, 7, Fig. 5b), wherein each of the sample compartments comprise different biological recognition elements, for the specific recognition and binding of different analyte (pg. 14, lines 11-12; pg. 21, lines 19-24) and are immobilized in 2-1000, which encompasses the recited five or more, discrete measurement areas in a two-dimensional array on the optical waveguide in the sample compartments (number of individual waveguiding regions, pg. 13, lines 7-8; recognition elements immobilized on waveguiding regions, pg. 14, lines 11-12; detection regions, pg. 13, lines 21-22), wherein the measurement areas are in optical interaction with an excitation light emanating from the optical waveguide as part of a sensor platform which forms a demarcation of the sample compartments (pg. 7, lines 18-19; pg. 8, lines 22-24; pg. 17, lines 5-6), wherein the sample compartments are operable to be cleared of received sample.

Regarding claims 2 and 3, Neuschäfer et al. teach one measurement area being used for referencing (quality control, pg. 36, lines 23-24). Neuschäfer et al. also teach several measurement areas being used for referencing (control molecules, used for referencing, are immobilized in strips on five regions, pg. 36, lines 25-26).

With respect to claim 4, Neuschäfer et al. teach measurement areas in optical interaction with an evanescent field of excitation light guided in the planar optical waveguide (pg. 6, last line-pg. 7, line 3).

Regarding claims 5 and 6, Neuschäfer et al. teach the optical waveguide being self-supporting (pg. 5, lines 24-29) and part of the sensor platform being a multi-mode or single-mode waveguide comprising glass (pg. 15, line 10).

With respect to claims 7-13, Neuschäfer et al. teach an optical film waveguide comprising a first optically transparent layer on a second optically transparent layer made of glass with lower refractive index than the first layer (pg. 10, lines 12-17; pg. 15, lines 19-22) and wherein the refractive index of the first optically transparent layer is higher than 2.0 (pg. 16, lines 2-3), which encompasses the recited greater than 1.8, and is made of TiO_2 (pg. 15, lines 4-5). Neuschäfer et al. also teach the thickness of the first optically transparent layer between 40 and 1000 nm (pg. 15, lines 7-8), which encompasses the recited between 40 and 300 nm. Neuschäfer et al. also teach an additional optically transparent layer between the first and second optically transparent layer and having a thickness of less than 10,000 nm (pg. 15, lines 17-18), which encompasses the recited range of 5-10,000 nm, wherein the purpose of the additional layer is to reduce the surface roughness below the first optically transparent layer (pg. 15, lines 18-22).

Regarding claims 14-16, Neuschäfer et al. teach an adhesion-promoting layer deposited on the first optically transparent layer for the immobilization of biological recognition elements (pg. 19, lines 14-16), having a thickness of less than 50 nm (pg. 19, lines 17-18), which is encompassed by the recited less than 200 nm, and comprising chemical compounds of silanes (pg. 12, lines 15-20).

With respect to claims 17-18 and 81, Neuschäfer et al. teach laterally separated measurement areas (Fig. 3-5; pg. 13, last paragraph-pg. 14, line 2; pg. 18, lines 12-13). Although Neuschäfer et al. do not specifically teach the areas generated by laterally selective deposition of

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biological recognition elements, such a limitation does not appear to physically further limit the product recited in claims 1 and 17. It is unclear what product limitations are set forth by areas generated by laterally selective deposition, and since the same product limitations are taught by Neuschäfer et al. as recited in claims 1 and 17, the product of Neuschäfer et al. would be capable of comprising measurement areas generated by laterally selective deposition of biological elements. Neuschäfer et al. teach a method of deposition comprising ink jet spotting (pg. 18, lines 15-21).

Regarding claims 19 and 20, Neuschäfer et al. teach a biological recognition element being nucleic acids (pg. 21, lines 19-24), including DNA which comes from a cell and is considered a cell fragment.

With respect to claims 21-22, Neuschäfer et al. teach “chemically neutral” compounds such as bovine serum albumin, to minimize nonspecific binding (pg. 37, lines ; pg. 40, lines).

Regarding claims 23-26, Neuschäfer et al. teach incoupling or outcoupling of light performed by one or more grading structures (pg. 17, lines 5-6), and the grating structures in the first optically transparent layer having the same or different periodicity (pg. 17, lines 6-8).

With respect to claims 27-29, Neuschäfer et al. teach grating structures having a period of 200 nm – 1000 nm and a grating modulation depth of 3-100 nm (pg. 16, last paragraph), wherein the ration of the modulation dept to thickness of the first optically transparent layer is equal to or smaller than 0.2 (pg. 16, lines 11-12). Neuschäfer et al. further teach grating structures being rightangular with a periodic modulation of the refractive index in the planar optically transparent layer (rectangular, pg. 16, lines 16-17).

Regarding claim 30, Neuschäfer et al. teach a thin metal layer, gold, deposited between the first optically transparent layer and the immobilized biological recognition elements, wherein the thickness of the metal can be excited at a luminescence wavelength (pg. 11, lines 11-15).

With respect to claims 31-34, Neuschäfer et al. teach a grating structure having a diffractive grating with a uniform period (pg. 16, last paragraph) or a multi-diffractive grating (1-3 modes is a multi-diffractive grating, pg. 18, lines 1-2). Neuschäfer et al. further teach grating structures located outside the region of the sample compartments (grating located in and out of sample compartment, 3,3', Fig. ; pg. 9, lines 23-24) and grating structures extend over a range of multiple sample compartments (one periodicity indicates one grating structure over all sample compartments; pg. 16, last paragraph).

Regarding claims 38, 39, 82 and 83, Neuschäfer et al. teach a sealing material, comprising polysiloxane (pg. 12, lines 15-20), and is self-adhesive (pg. 34, lines 4-7).

With respect to claims 40, 42, 84 and 86, Neuschäfer et al. teach 2-100 measurement areas in one sample compartment (pg. 13, lines 22-23), which is encompassed by the recited 2-1000 measurement areas. Neuschäfer et al. also teach the sample compartments having a volume of 0.07 ml (pg. 34, line 5), which is encompassed by the recited 100 nl-1ml.

Regarding claims 43 and 87, Neuschäfer et al. teach a side facing away from an optically transparent layer, and being closed except for inlet and outlet openings for the supply or removal of samples (Fig. 5b; pg. 14, lines 6-12). Neuschäfer et al. fail to teach supply or removal of samples performed in a closed flow-through system, wherein common inlet and outlet openings are addressed row by row or column by column. However, such limitations do not appear to further limit the product limitations recited in claims 1, 43 and 87. Therefore, since Neuschäfer

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et al. teach the product limitations recited in claims 1, 43 and 87, the device of Neuschäfer et al. would be capable of performing such supply or removal of samples.

With respect to claims 44 and 88, Neuschäfer et al. fail to teach supply of samples affected by pressure differences or electric potentials. However, such a limitation does not appear to provide further product limitations to the product of claims 1 and 44. Therefore since Neuschäfer et al. teach the recited product limitations of claims 1 and 44, the device of Neuschäfer et al. would be capable of affecting the sample supply with the recited pressure differences or electric potentials.

Regarding claims 45-47 and 89-91, Neuschäfer et al. teach sample compartments having openings for locally addressed supply or removal of samples or other reagents at the side facing away from the optically transparent layer (inlet and outlet openings for solutions, pg. 14, lines 6-12). Neuschäfer et al. further teach compartments provided for reagents (reagents are contained in a compartment when introduced into the flow-through device, pg. 36, lines 8-10). Neuschäfer et al. also teach mechanically recognizable marks are provided on the sensor platform, in order to facilitate the adjustment in an optical system (depression cut for waveguide so waveguiding layer faces the cannels and facilitates optical detection, pg. 37, lines 7-13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuschäfer et al., as applied to claim 1, in view of Hashimoto et al. (US 6,480,639).

Neuschäfer et al., as applied to claim 23, teach a device comprising a tight sealing layer, but fail to teach the material being optically transparent or optically absorbent.

Hashimoto et al. teach a sealing layer being optically transparent or absorbent (col. 16, lines 54-63), in order to block leakage lights from the light emitting device.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Neuschäfer et al., an absorbent or transparent sealing layer as taught by Hashimoto et al., in order to more effectively seal the optical device and fix optical fibers.

Hashimoto et al. also teach a 2 layer system wherein a first transparent layer is brought into contact with a sensor platform (col. 16, line 54-57), and a second absorbent layer is present and located more remotely from the sensor platform (col. 16, lines 58-63).

6. Claims 41 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuschäfer et al. (WO 96/35940).

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Neuschäfer et al., as applied to claim 1, teach a device comprising a sample compartment occupying an area of 9 mm^2 (pg. 36, last 2 lines). Neuschäfer et al. fail to teach an area of $0.001 - 6 \text{ mm}^2$. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation” Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation.” Id. at 458, 105 USPQ at 236-237. The “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” Since applicant has not disclosed that the specific limitations recited in instant claims 41 and 85 are for any particular purpose or solve any stated problem, and the prior art teaches that the measurement area can be varied in order to accommodate different sample volumes, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the flow-through device art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Melanie Yu
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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